REMARKS/ARGUMENTS

In response to the pending Office Action, Applicants provide the following remarks to address the issues cited by the Examiner. Applicants' remarks with respect to the Examiner's rejections are believed to be sufficient to overcome these rejections and, therefore, Applicants' silence to any assertions by the Examiner in the Office Action or certain requirements that may be applicable to such rejections (e.g., whether a reference constitutes prior art, motivation to combine references, assertions as to dependent claims, etc.) is not a concession by Applicants that such assertions are accurate or such requirements have been met, and Applicants reserve the right to analyze and dispute such assertions/requirements in the future.

Claims 1-4, 9-22, 27-40 and 45-54 are currently pending. Claims 1, 19 and 37 have been amended and no claims have been added or cancelled. It is respectfully submitted that no new matter has been introduced by these amendments, as support therefor is found throughout the specification, claims and drawings as originally filed. In view of the above amendments and the following remarks, Applicants submit that all of the pending claims are allowable and respectfully request reconsideration of the present application.

Rejections –35 U.S.C. § 103(a)

Claims 1-4, 9, 10, 13, 17, 19-22, 27, 28, 31, 35, 37- 40, 45, 46 and 53 stand rejected as being unpatentable over Vancaillie et al. (U.S. Pat. No. 5,095,917; hereinafter referred to as "Vancaillie") in view of Tay et al. (U.S. Pat. No. 5,810,810; hereinafter referred to as "Tay") and further in view of Zeluff (U.S. Pat. No. 4,606,336; hereinafter referred to as "Zeluff"); claims 11, 12, 15, 16, 29, 30, 33, 34, 47, 48, 51 and 52 stand rejected as being unpatentable over Vancaillie in view of Tay and further in view of Zeluff and Barbacci (U.S. Pat. No. 5,531,741; hereinafter referred to as "Barbacci"); and claims 14, 18, 32, 36, 50 and 54 stand rejected as being unpatentable over Vancaillie in view of Tay and further in view of Zeluff and Brundin (U.S. Pat. No. 4,509,504; hereinafter referred to as "Brundin"). The Examiner's grounds for rejection are hereinafter traversed and reconsideration is respectfully requested.

In order to support a rejection under 35 U.S.C. § 103(a), the rejected claims must be obvious in light of the cited references. Furthermore, "[t]o establish prima facie obviousness of a claimed

invention, all the claim limitations must be taught or suggested by the prior art." In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). However, the Supreme Court has made it clear that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. KSR International Co. v. Teleflex, Inc., 127 S. Ct. 1731, 82 USPQ2d 1389 (2007); an Examiner must provide some reasoning to combine the references. Id. at 1741, 82 USPQ2d at 1396.

Vancaillie describes a transuterine sterilization procedure which involves destruction of the mucosa of the uterotubal junction followed by insertion of a biodegradable plug. The mucosal destruction provokes an inflammatory reaction and the plug serves as a substrate to guide the healing process toward occlusion instead of recanalization. As described at column 3, lines 36-42, the Vancaillie procedure relies on cells, such as macrophages, *to digest the material the plug is made of*, leaving behind a dense structure of fibers known as scar tissue in the uterotubal junction, resulting in *irreversible occlusion* of the tubal lumen. The Examiner admits that Vancaillie fails to disclose the utilization of a foam plug, as recited in independent claims 1, 19 and 37.

To overcome this deficiency of Vancaillie, the Examiner combines the teachings of Zeluff; however, the Applicant's respectively submit that this combination is unfounded. In stark contrast to the teachings of Vancaillie, Zeluff teaches a reversible sterilization process that utilizes a rigid, non-porous hub surrounded by a ring of porous material. The presence of non-porous material prevents fibroblast ingrown therein, which is important to the reversibility of the sterilization process. The Applicants respectfully submit that one skilled in the art would not look to the teachings of Zeluff to arrive at the claimed invention. To do so would conflict with the teachings of Vancaillie and, in fact, change Vancaillie's principle of operation, which is to completely digest the plug over time (see col. 3, line 38), leaving behind a dense structure of scar tissue in the lumen of the uterotubal junction including the area where the plug was inserted (see col. 3, lines 40-42), to ultimately effectuate *irreversible* sterilization. Zeluff, on the other hand, relies on the fact that the rigid non-pourous hub is never digested so that the Zeluff ostial occlusion device can be removed to *reverse* sterilization. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959); MPEP 2143.01.

Therefore, Applicants respectfully submit that Zeluff does not overcome the deficiencies in the combination of Vancaillie (and Taye), as the teachings of Zeluff are not sufficient to render the claims obvious for at least the reasons advanced above -- i.e. that one skilled in the art would not look to the teachings of Zeluff (a reversible sterilization process) in view of Vancaillie (an irreversible sterilization process) to arrive at the claimed invention and, further, the proposed modification would change the principle of operation of the Vancaillie device.

Furthermore, the Applicants respectfully submit that none of the cited references, alone or in combination, teach, disclose or otherwise suggest the step of retracting the heating element (or wounding element) and substantially simultaneously installing a plug into the target (or wounded) segment of the ovarian pathway, while substantially maintaining the position of the catheter body relative to the target (or wounded) segment, as respectively recited in independent claims 1, 19 and 37, as amended. To the contrary, Vancaillie specifically teaches an instrument having a hollow tube 30 containing two or three plugs 32 and a piston 34 slidably disposed therein. During the procedure, "the piston 34 of the instrument is activated and the instrument [is] *simultaneously* slightly withdrawn…result[ing] in the release of one plug 32… at the exact level of the destroyed mucosa of the uterotubal junction" (Col. 3, lines 15-19; emphasis added). Hence, one must *simultaneously* activate the piston 34 and withdraw the instrument (i.e. hollow tube 30) to ensure that the plugs 32 are accurately implanted at the desired location. Such a procedure invites error, as the person performing the procedure could miss the target location, for example, by erroneously commencing withdrawal of the device (i.e. hollow tube 30) before actuating the piston to eject a plug 32 and/or eject a plug 32 before commencing withdrawal of the device (i.e. hollow tube 30). In other words, precise timing and control are required to ensure accurate implantation. The present invention overcomes this disadvantage by eliminating the need to withdraw (or control movement of) the catheter; that is, the catheter remains in position relative to the target location and only the heating element is moved (i.e. retracted) to expose and install a plug precisely at the desired target location.

Regarding the other cited references, Applicants respectfully submit that none of the references, alone or in combination with each other and/or Vancaillie, meet the terms of the claimed invention and, as such, neither anticipate the claimed invention nor render the claimed invention obvious. Taye, at most, teaches an apparatus for sealing vascular punctures without any consideration of retracting the electrodes 50 to facilitate substantial simultaneous installation of a

plug for occluding an ovarian pathway for female sterilization. Zeluff, at most, teaches the installation of an occlusion device 10 by extending a separate carrier control device 32 through a hysteroscope 28, and then actuating levers 36 to linearly displace a shaft 37 proximally (i.e. the shaft is not retracted) to, in turn, forwardly eject the occlusion device (see, for example, col. 5, lines 12-52). Further, Zeluff is silent with respect to applying an RF electrode array to a target segment of the ovarian pathway. Brundin, at most, teaches using a hysteroscope to locate the oviduct opening into the uterus and then implanting a water-swellable article 2 therein; Brundin provides no disclosure or enablement regarding how the article is delivered and implanted. Lastly, Barbacci, at most, teaches a radial light emitting ureteral stent without any contemplation of the claimed method.

Therefore, for at least the reasons advanced above, Applicants respectfully submit that independent claims 1, 19 and 37 define patentably over the prior art of record. Withdrawal of the rejections of claims 1, 19 and 37 is respectfully requested. Because dependent claims 2-4, 9-18, 20-22, 27-36, 38-40 and 45-54 depend either directly or indirectly from one of independent claims 1, 19 and 37, Applicants respectfully submit that said dependent claims define patentably over the prior art of record for at least the same reasons set forth above in support of the patentability of claims 1, 19 and 37 and for reciting additional patentable subject matter. Withdrawal of the rejections of claims 2-4, 9-18, 20-22, 27-36, 38-40 and 45-54 is respectfully requested.

Conclusion

In light of the above Remarks, Applicants respectfully request that a timely Notice of Allowance be issued in this case. If the Office should have any questions or other issues regarding this matter, the Office is cordially invited to contact the undersigned attorney.

Applicants believe that a three-month extension of time and fee are required with this submission. Please consider this a request for a three-month extension of time therefor and authorization to charge Deposit Account No. 50-2855 accordingly. If any additional fees are required in connection with this application, authorization is hereby given to charge Deposit Account No. 50-2855 accordingly.

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Respectfully submitted,

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